UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE: DAVOL, INC./C.R. BARD, INC., POLYPROPYLENE HERNIA MESH PRODUCTS LIABILITY LITIGATION

Case No. 2:18-md-2846

JUDGE EDMUND A. SARGUS, JR.
Magistrate Judge Kimberly A. Jolson

This document relates to:
Milanesi, et al. v. C.R. Bard, Inc., et al.
Case No. 2:18-cv-01320

DISPOSITIVE MOTIONS ORDER No. 5

Before the Court is Defendants C.R. Bard and Davol's Renewed Motion for Judgment as a Matter of Law. (ECF No. 384.) Defendants argue that they are entitled to judgment as a matter of law as to Plaintiffs Antonio Milanesi and Alicia Morz de Milanesi's claims of negligent design defect and loss of consortium. For the reasons stated below, Defendants' Motion (ECF No. 384) is **DENIED**.

I. Background[1]

Plaintiffs' case is the second bellwether trial selected from thousands of cases in this multidistrict litigation ("MDL") against Defendants. The Judicial Panel on Multidistrict Litigation described the cases in this MDL as "shar[ing] common factual questions arising out of allegations that defects in defendants' polypropylene hernia mesh products can lead to complications when implanted in patients, including adhesions, damage to organs, inflammatory and allergic responses,

[1] For a more complete factual background, the reader is directed to the Court's summary judgment opinion and order in this case *Milanesi v. C.R. Bard*, Case No. 2:18-cv-01320. (ECF No. 167.) All docket citations are to the *Milanesi* case, 2:18-cv-1320, unless otherwise noted.

foreign body rejection, migration of the mesh, and infections." (No. 2:18-md-02846, ECF No. 1 at PageID #1–2.)

Plaintiffs brought this action to recover for injuries sustained as a result of the implantation of the Ventralex Large Hernia Patch, alleging that Defendants knew of the risks presented by the device but marketed and sold it despite these risks and without appropriate warnings. After summary judgment, the following claims remained for trial: strict liability design defect, negligent design defect, negligent failure to warn, negligent misrepresentation, fraudulent misrepresentation, loss of consortium, and punitive damages. Trial commenced on March 21, 2022 and lasted for approximately four weeks. At the conclusion of Defendants' case on April 12, 2022, Defendants moved for judgment as a matter of law. (ECF No. 371.) On April 15, 2022, the jury returned a verdict for Defendants on Plaintiffs' claims of strict liability design defect, negligent failure to warn, negligent misrepresentation, and fraudulent misrepresentation. The jury returned a verdict for Plaintiffs on their claims of negligent design defect, with an award of $250,000, and loss of consortium, with an award of $5,000. The jury did not award punitive damages. On May 13, 2022, Defendants filed a Renewed Motion for Judgment as a Matter of Law as to Plaintiffs' negligent design defect and loss of consortium claims. (ECF No. 384.)

II. Legal Standard

A party may move for judgment as a matter of law under Federal Rule of Civil Procedure 50 when the opposing party has been fully heard and before the case is submitted to the jury. Fed. R. Civ. P. 50(a)(1) & (2). If the Court does not grant a motion for judgment as a matter of law made under Rule 50(a), "the court is considered to have submitted the action to the jury subject to the court's later deciding the legal questions raised by the motion." Fed. R. Civ. P. 50(b). The movant may file a renewed motion within 28 days of the entry of judgment. *Id.* In ruling on the

renewed motion, the Court may allow judgment on the verdict, order a new trial, or direct the entry of judgment as a matter of law. *Id.* The Court may grant the motion if "the court finds that a reasonable jury would not have a legally sufficient evidentiary basis to find for the party on that issue." Fed. R. Civ. P. 50(a)(1). The same standard for summary judgment motions applies to motions for judgment as a matter of law. *White v. Burlington N. & Santa Fe R. Co.*, 364 F.3d 789, 794 (6th Cir. 2004) (en banc) (citing *Reeves v. Sanderson Plumbing Prods., Inc.*, 530 U.S. 133, 150 (2000)). The Court must review the entire record and "draw all reasonable inferences in favor of the nonmoving party, and [it] may not make credibility determinations or weigh the evidence." *McCombs v. Meijer, Inc.*, 395 F.3d 346, 352 (6th Cir. 2005) (quoting *Reeves*, 530 U.S. at 150). This means that the Court "must disregard all evidence favorable to the moving party that the jury is not required to believe." *White*, 364 F.3d at 794–95 (quoting *Reeves*, 530 U.S. at 151). "District courts should grant judgment as a matter of law only if a complete absence of proof exists on a material issue in the action, or if no disputed issue of fact exists on which reasonable minds could differ." *LaPerriere v. Int'l Union, United Auto., Aerospace, & Agric. Implement Workers of Am.*, 348 F.3d 127, 132 (6th Cir. 2003) (quoting *Clark v. Chrysler Corp.*, 310 F.3d 461, 479 (6th Cir.2002), *vacated on other grounds by Chrysler Corp. v. Clark* 124 S. Ct. 102 (2003); *see also In re E.I. Du Pont De Nemours & Co.*, No. 2:13-md-2433, 2015 WL 5822663, at *2 (S.D. Ohio Oct. 1, 2015).

III. Analysis

Defendants' Motion raises several issues that the Court previously addressed in Dispositive Motions Order ("DMO") No. 3 (ECF No. 167) granting in part and denying in part Defendants' Motion for Summary Judgment. In DMO No. 3, the Court addressed Defendants' arguments regarding to Dr. Krpata's buckling causation opinions, the risk-utility and consumer expectation

tests, and whether the Ventralex was "state of the art" in 2007. In Defendants' renewed Motion, they seek judgment as a matter of law on Plaintiffs' negligent design and loss of consortium claims.

A. Negligent Design Defect

Defendants claim that Plaintiffs failed to prove defect and causation, that comment k applies and barred Plaintiffs' defect claims, that the Ventralex was state of the art in 2007, and that Plaintiffs failed to prove design defect or causation with competent expert testimony.

i. Defect

At trial, the Court instructed the jury on both the consumer expectations test and on the risk-utility tests for Plaintiffs' design defect claims. The consumer expectations test asks whether a product failed to perform as safely as an ordinary consumer would expect when used as intended or in a manner reasonably foreseeable by the manufacturer, and the risk-utility test asks whether the risks of the product outweigh its benefits. *See* Jury Instruction No. 18. The parties dispute whether, or to what extent, *Aubin v. Union Carbide Corp.* should apply. In *Aubin*, the Supreme Court of Florida "in approaching design defect claims, [] adhere[d] to the consumer expectations test." *Aubin v. Union Carbide Corp.*, 177 So. 3d 489, 510 (Fla. 2015). Defendants argue that *Aubin* "was not a complex medical device [case] and thus had no occasion to consider the question of the proper standard to apply in the medical device context" and instead "dealt with the question of what the default design defect standard should be." (ECF No. 384 at PageID #19270.) Plaintiffs counter that Defendants read *Aubin* too narrowly. According to Plaintiffs, the language in *Aubin* "did not state or suggest that its holding should be limited in any way." (ECF No. 389 at PageID #19506.)

Defendants claim that "in cases involving complex medical devices . . . controlling Florida law provides that *only* the risk-utility test may be utilized to determine whether a product has a

defective design." (ECF No. 384 at PageID #19268 (emphasis in original).) In support of this argument Defendants cite to *Cavanaugh v. Stryker Corp.*, 308 So. 3d 149 (Fla. Dist. Ct. App. 2020), *review denied,* No. SC21-219, 2021 WL 3485938 (Fla. Aug. 9, 2021). In *Cavanaugh*, the court determined that the consumer expectations test could not be logically applied in that case, "where the product in question [was] a complex medical device available to an ordinary consumer only as an incident to a medical procedure." *Id.* at 155. The court reasoned that "ordinary consumers would not be purchasing the [device] and would not have formed expectations regarding the product." *Id.* The proposed instruction "would have been misleading to the jury because it failed to inform the jury that the relevant expectations are those of the medical professional, not the ordinary consumer." *Id.* at 156.

The Court previously addressed this argument in DMO No. 3 (ECF No. 167), and its reasoning still applies here. At trial, the Court instructed the jury on both the risk-utility test and the consumer expectations test, with the relevant consumer being Mr. Milanesi's implanting surgeon, Dr. Gill. In Jury Instruction No. 18, the Court informed the jury that "[the Ventralex] is unreasonably dangerous because of its design if the Ventralex failed to perform as safely as an ordinary consumer, in this case Mr. Milanesi's implanting surgeon Dr. Gill, would expect when used as intended or in a manner reasonably foreseeable by the manufacturer, or the risk of danger in the design outweighs the benefits." The Court did not instruct the jury to consider the expectations of Plaintiffs as consumers of the Ventralex. Unlike the plaintiff's proposed instruction in *Cavanaugh*, the instruction in this case did not "fail[] to inform the jury that the relevant expectations are those of the medical professional, not the ordinary consumer." *Cavanaugh*, 308 So.3d at 156. Although *Cavanaugh* concluded that the proposed consumer expectations instruction did not apply to the complex medical device at issue, the court also noted

the possibility of an instruction like the one given in this case. The court stated that "[e]ven assuming that some version of the consumer expectations test should apply to complex medical products which are provided to a consumer through a learned intermediary, the standard instruction would need to be modified in order to inform the jury that *the relevant expectations are those of the health care professional*." *Id.* (emphasis added). That is exactly what this Court did in Jury Instruction No. 18. The language of the instruction made clear that the relevant expectations were those of Dr. Gill, not of Plaintiffs. The jury was properly instructed regarding Plaintiffs' design defect claims, and the Court cannot find "that a reasonable jury would not have a legally sufficient evidentiary basis to find for the party on that issue." Fed. R. Civ. P. 50(a)(1).

ii. Causation

Defendants allege that Plaintiffs "failed to introduce sufficient evidence demonstrating that any purported defect caused Mr. Milanesi's alleged injuries." (ECF No. 384 at PageID #19273.) Defendants point specifically to Plaintiffs' "degradation/biocompatibility theory" and "contracture/'buckling' assertions." (*Id.*) The Court previously addressed some of Defendants' arguments regarding buckling in DMO No. 3 (ECF No. 167) and Evidentiary Motions Order No. 17 (ECF No. 166).

Defendants first claim that "Plaintiffs introduced no evidence that any alleged degradation actually led to . . . [Mr. Milanesi's] fistula that led to infection." (ECF No. 384 at PageID #19273.) Defendants claim that Plaintiffs offered no testimony, expert or otherwise, linking alleged degradation of polypropylene to Mr. Milanesi's injuries. (*Id.*) Plaintiffs respond that Dr. Mays, Plaintiffs' biomaterials expert, testified that "polypropylene in the body triggers a foreign body response, which degrades the polypropylene, causing it to become hard, stiff, and brittle . . . [which] promotes shrinkage in the mesh." (ECF No. 389 at PageID #19510.) This shrinkage then

exposes the polypropylene side of the mesh to the viscera, damaging organs and other sensitive tissue. (*Id.*) According to Plaintiffs, Dr. Mays's testimony, in conjunction with Dr. Krpata's testimony, proved causation. Dr. Krpata testified that, based on his review of Mr. Milanesi's medical records, "the Ventralex curling and exposing bare polypropylene to Mr. Milanesi's small intestine caused Mr. Milanesi's fistula and infection." (*Id.*) Plaintiffs point out that under Florida law, a defect in a product need not be the only cause of injury and may be regarded as the legal cause of injury even though it operates in combination with some other cause. (*Id.* at PageID #15911 (citing Fla. Std. Jury Instr. (CIV) 403.12).) The Court finds Defendants' degradation/biocompatibility argument to be lacking. Considering Dr. Mays's testimony, in conjunction with Dr. Krpata's specific causation opinions, the Court cannot find that a reasonable jury would not have a legally sufficient evidentiary basis to find for Plaintiffs on that issue.

Defendants also claim that Plaintiffs' expert Dr. Krpata acknowledged that "there are inherent risks with intraperitoneal placement[,] . . . that no device is risk free, and that he had no study showing higher risks of complications with Ventralex." (ECF No. 384 at PageID #19274.) Therefore, Defendants argue, Plaintiffs and Dr. Krpata failed to establish that "it was allegedly defective features of [*Defendants'*] *product*, as opposed to the inherent risks with intraperitoneal placement or all intraperitoneal mesh, that *caused* the specific complication Mr. Milanesi suffered." (*Id.* (emphasis in original).) Plaintiffs claim that Defendants misstate Dr. Krpata's testimony. Plaintiffs point to Dr. Krpata's testimony that "if a different device was used, [Mr. Milanesi] could have had a different outcome." (ECF No. 389 at PageID #19511.) Plaintiffs also note that "[i]n support of his opinion, Dr. Krpata conducted a differential diagnosis through which he ruled out other potential causes of Mr. Milanesi's injury, including medical history, implant technique, and adhesions prior to implantation." (*Id.* at PageID #19512.) Therefore, Plaintiffs

claim that they presented "more than sufficient evidence" of causation. This Court agrees. Simply because Dr. Krpata acknowledged that all medical procedures and devices have risks does not mean that "a complete absence of proof exists . . . or [that] no disputed issue of fact exists on which reasonable minds could differ." *LaPerriere*, 348 F.3d at 132 (internal citations omitted).

iii. Comment K

According to Defendants, comment k to § 402A of Restatement Second of Torts applies and barred Plaintiffs' defect claims. (ECF No. 384 at PageID #19275.) Comment k states that:

> There are some products which, in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use. These are especially common in the field of drugs. An outstanding example is the vaccine for the Pasteur treatment of rabies, which not uncommonly leads to very serious and damaging consequences when it is injected. Since the disease itself invariably leads to a dreadful death, both the marketing and the use of the vaccine are fully justified, notwithstanding the unavoidable high degree of risk which they involve. Such a product, properly prepared, and accompanied by proper directions and warning, is not defective, nor is it *unreasonably* dangerous. The same is true of many other drugs, vaccines, and the like, many of which for this very reason cannot legally be sold except to physicians, or under the prescription of a physician. It is also true in particular of many new or experimental drugs as to which, because of lack of time and opportunity for sufficient medical experience, there can be no assurance of safety, or perhaps even of purity of ingredients, but such experience as there is justifies the marketing and use of the drug notwithstanding a medically recognizable risk. The seller of such products, again with the qualification that they are properly prepared and marketed, and proper warning is given, where the situation calls for it, is not to be held to strict liability for unfortunate consequences attending their use, merely because he has undertaken to supply the public with an apparently useful and desirable product, attended with a known but apparently reasonable risk.

Restatement (Second) of Torts § 402A (1965). Comment k "applies to products which current knowledge and technology cannot make safe for their ordinary use, but for which society has a need great enough to justify using the product despite its dangers." *Adams v. G.D. Searle & Co.*, 576 So. 2d 728, 731 (Fla. Dist. Ct. App. 1991). Comment k has been applied in medical device products liability actions in Florida. *See id.*; *Tillman v. C.R. Bard, Inc.*, 96 F. Supp. 3d 1307 (M.D.

Fla. 2015). Defendants claim that testimony from Dr. Gill, Mr. Milanesi's implanting surgeon, "laud[ing] the Ventralex's composite design," and testimony from Dr. Krpata that "made plain that there is no safer alternative design for the Ventralex" shows that Defendants met their burden in showing that comment k barred Plaintiffs' design defect claim. (ECF No. 384 at PageID #19275.)

Plaintiffs counter that the cases cited by Defendants state that comment k "applies to *strict liability* design defect claims." (ECF No. 389 at PageID #19512 (emphasis in original).) In *Adams*, the court noted that "[c]omment k protects the manufacturers of certain products from strict liability for design defects" and "follow[ed] those courts which hold that comment k is an affirmative defense to a strict liability claim." *Adams*, 576 So.2d at 731, 732–33. The court in *Tillman* also acknowledged that "comment k 'is an affirmative defense to a strict liability claim.'" *Tillman*, 96 F.Supp.3d at 1340 (quoting *Adams*, 576 So.2d at 733). In fact, comment k itself says that the seller of a product "is not to be held to *strict liability* for unfortunate consequences attending [the device's] use." Restatement (Second) of Torts § 402A (1965) (emphasis added).

Defendants argue in response that "defect very clearly is an element of a negligent design claim under Florida law and comment k retains its persuasive force in this context, too." (ECF No. 390 at PageID #19604–05.) However, comment k specifically refers to strict liability, and the jury found for Defendants on Plaintiffs' strict liability design defect claim. The Court is not persuaded that comment k applies to Plaintiffs' negligent design defect claim. Therefore, the Court finds that Defendants are not entitled to judgment as a matter of law on the basis of comment k.

iv. State of the Art

Defendants next argue that the Ventralex was state of the art when sold in 2007. Defendants point to their expert and fact witnesses' testimony to show that the Ventralex complied

with the best known and available technology at the time. (ECF No. 384 at PageID #19278.) Defendants take issue with the rebuttal testimony of Plaintiffs' expert, Dr. Mays, and claim that the testimony was "improperly admitted in violation of Rule 26." (*Id.* at PageID #19279.) However, the Court heard and ruled on Defendants' objections to Dr. Mays's rebuttal testimony at trial and declines to revisit that ruling.

Additionally, as Plaintiffs point out, whether the Ventralex was state of the art is simply one factor for the finder of fact to consider in a design defect action. (ECF No. 389 at PageID #19515.) Florida's "state-of-the-art defense for products liability" statute states that "[i]n an action based upon defective design, brought against the manufacturer of a product, the finder of fact shall consider the state of the art of scientific and technical knowledge and other circumstances that existed at the time of manufacture, not at the time of loss or injury." Fla. Stat. § 768.1257. Defendants claim that Plaintiffs' arguments run contrary to the "*shall* consider" language of § 768.1257, which Defendants claim "is dispositive of Plaintiffs' defect claim." (ECF No. 390 at PageID #19606.) However, the Court instructed the jury with language directly from the Florida statute. *See* Jury Instruction No. 18 ("In deciding whether the Ventralex was defective because of a design defect, you shall consider the state-of-the-art of scientific and technical knowledge and other circumstances that existed at the time of the Ventralex's manufacture, not at the time of any injury to Plaintiffs. A product is 'state of the art' if it is based on the best known and available technology."). Defendants offer no convincing arguments or authority to show that whether the Ventralex was state of the art is dispositive, or that the jury "[did] not have a legally sufficient evidentiary basis to find for [Plaintiffs] on that issue." Fed. R. Civ. P. 50(a)(1).

v. Expert Testimony

Finally, Defendants claim that Plaintiffs failed to prove design defect or causation with

competent expert testimony. In doing so, Defendants "renew [their] *Daubert* challenge[s], and associated sufficiency of the evidence arguments, regarding the testimony of Dr. Mays and Dr. Krpata." (ECF No. 384 at PageID #19280.) Defendants note that the Court previously addressed this issue at summary judgment and "agree that nothing has changed," and state that they are renewing the challenge in order to preserve it for appeal. (*Id.* at PageID #19280–81.) Defendants present no argument that would compel the Court to revisit its summary judgment and *Daubert* rulings on this issue, and therefore judgment as a matter of law is not warranted.

B. Loss of Consortium

The parties appear to agree that the loss of consortium claim is a derivative claim. (*See* ECF No. 389 at PageID #19519; ECF No. 390 at PageID #19609.) Therefore, Defendants argue that because they are entitled to judgment as a matter of law on the negligent design claim, judgment of a matter of law is also warranted on Mrs. Milanesi's loss of consortium claim. (ECF No. 384 at PageID #19281.) However, because the Court finds that Defendants are not entitled to judgment as a matter of law on Plaintiffs' negligent design defect claim, Defendants are not entitled to judgment as a matter of law on Mrs. Milanesi's loss of consortium claim.

IV. Conclusion

For the reasons set forth above, Defendants' Renewed Motion for Judgment as a Matter of Law (ECF No. 384) is **DENIED**.

IT IS SO ORDERED.

7/8/2022
DATE

s/Edmund A. Sargus, Jr.
EDMUND A. SARGUS, JR.
UNITED STATES DISTRICT JUDGE